OFFICE OF SPECIAL MASTERS

(Filed: June 30, 2005)

TERESA MOBERLY, as mother and next friend of her daughter, MOLLY MOBERLY, Petitioner,	)	
v.	)	No. 98-0910V
	)	PUBLISH
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	

DECISION[1]

Petitioner, Teresa Moberly (Ms. Moberly), as next friend of her daughter, Molly Moberly (Molly), seeks compensation under the National Vaccine Injury Compensation Program (Program).[2] Molly suffers an intractable seizure disorder accompanied by developmental delay. *See, e.g.*, Petitioner's exhibit (Pet. ex.) 44 at 34-35. Ms. Moberly attributes Molly's condition to a diphtheria-pertussis-tetanus (DPT) vaccination that Molly received on September 17, 1996. Petition (Pet.) at 1. Ms. Moberly concedes that Molly's condition does not qualify for the statutory presumption of causation afforded by § 300aa-11(c)(1)(C)(i); § 300aa-13(a)(1)(A); the Vaccine Injury Table (Table), 42 C.F.R. § 100.3(a)(II) (2004); and the qualifications and aids to interpretation (QAI), 42 C.F.R. § 100.3(b)(2) (2004), that apply to the Table governing the petition. *See, e.g.*, Petitioner's Prehearing Memorandum (P. Prehearing Memo) at 1. Thus, Ms. Moberly acknowledges that she must prove

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[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" will be available to the public. *Id.*

[2] The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

that Molly's September 17, 1996 DPT vaccination caused actually Molly's condition. *See* P. Prehearing Memo at 1.

The parties stipulate that they do not dispute the facts "as reflected in [Molly's] medical records." Joint Status Report, filed January 10, 2003, at 1. Therefore, the special master convened a hearing limited to medical issues. Marcel Kinsbourne, M.D. (Dr. Kinsbourne), testified for Ms. Moberly. Robert J. Baumann, M.D. (Dr. Baumann), testified for respondent.

THE LEGAL STANDARD

To prevail, Ms. Moberly must demonstrate by the preponderance of the evidence that (1) "but for" the administration of Molly's September 17, 1996 DPT vaccination, Molly would not have been injured, and (2) Molly's September 17, 1996 DPT vaccination "was a substantial factor in bringing about" Molly's injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[3] The United States Court of Appeals for the Federal Circuit (Federal Circuit) has described Ms. Moberly's burden as "heavy." *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove legal cause. *Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992). Rather, Ms. Moberly must present "a medical theory," supported by "[a] reliable medical or scientific explanation," establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant*, 956 F.2d at 1148; *see also Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)). "The analysis undergirding" the medical or scientific explanation must "fall within the range of accepted standards governing" medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Ms. Moberly's medical or scientific explanation need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. But, Ms. Moberly's medical or scientific explanation must be "logical" and "probable," given "the circumstances of the particular case." *Knudsen*, 35 F.3d at 548-49.

According to the Federal Circuit, "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen v. Secretary of HHS*, 35

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[3] The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g.*, *Thornton v. Secretary of HHS,* 35 Fed. Cl. 432, 440 (1996); *see also In re Winship,* 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), *quoting* F. James, CIVIL PROCEDURE 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence standard. *Snowbank Enter. v. United States,* 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff'd*, 73 F.3d 381 (Fed. Cir. 1995).

F.3d at 549.[4] Applying the Federal Circuit's guidance, some special masters have adopted in cases alleging DPT vaccine-related neurological injuries a test based upon the National Childhood Encephalopathy Study (NCES) published in Great Britain in 1981;[5] a report produced in 1991 by the Institute of Medicine (IOM)--the august division of the National Academy of Sciences (NAS) that Congress designated to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines, *see* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986);[6] the ten-year follow-up study to the NCES published in 1993;[7] and a report produced in 1994 by the IOM.[8] *See, e.g.*, *Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 (Fed. Cl. Spec. Mstr. Jan. 23, 1998); *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 (Fed. Cl. Spec. Mstr. June 23, 1999); *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000); *Raj v. Secretary of HHS*, No. 96-0294V,

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[4] However, in most actual causation cases in the Program, petitioners are not able to adduce epidemiological evidence regarding a vaccination and an injury. As a result, many special masters have struggled over the years to articulate the proper method of analyzing actual causation cases that lack epidemiological evidence regarding a vaccination and an injury. *See e.g.*, *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001); *see also Pafford v. Secretary of HHS*, 64 Fed. Cl. 19 (2005), *appeal docketed* No. 05-5105 (Fed. Cir. Apr. 12, 2005). A judge of the United States Court of Federal Claims has advanced recently a "rule of reason." *Pafford*, 64 Fed. Cl. at 31. The judge posits that in appropriate circumstances, proof of biologic plausibility between a vaccine and an injury; proof that an injury occurred within a medically-acceptable time period following vaccination; and proof eliminating other potential causes for the injury may satisfy a petitioner's burden. *See id.*

[5] *See* R. Alderslade, *et al.*, *The National Childhood Encephalopathy Study: A Report on 1000 Cases of Serious Neurological Disorders in Infants and Young Children from the NCES Research Team*, *in* UNITED KINGDOM DEPARTMENT OF HEALTH AND SOCIAL SECURITY, WHOOPING COUGH: REPORTS FROM THE COMMITTEE ON SAFETY OF MEDICINES AND THE JOINT COMMITTEE ON VACCINE AND IMMUNIZATION 79-184 (Her Majesty's Stationery Office 1981).

[6] *See* Christopher P. Howson, *et al.*, INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES (National Academy Press 1991) (1991 IOM Report).

[7] *See* Nicola Madge, *et al.*, *The National Childhood Encephalopathy Study: A 10-year Follow-up: A Report on the Medical, Social, Behavioural and Educational Outcomes After Serious, Acute, Neurological Illness in Early Childhood*, *in* DEVELOPMENTAL MEDICINE AND CHILD NEUROLOGY Vol. 35, No. 7, Supp. No. 68 at 1-117 (July 1993); *see also* David Miller, *et al.*, *Pertussis Immunisation and Serious Acute Neurological Illnesses in Children*, 307 BRITISH MEDICAL JOURNAL 1171-1176 (1993).

[8] *See* Kathleen R. Stratton, *et al.*, INSTITUTE OF MEDICINE, DPT VACCINE AND CHRONIC NERVOUS SYSTEM DYSFUNCTION: A NEW ANALYSIS (National Academy Press 1994) (1994 IOM Report).

2001 WL 963984 (Fed. Cl. Spec. Mstr. July 21, 2001); *but see Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673 (Fed. Cl. Spec. Mstr. May 29, 2003); *Bruesewitz v. Secretary of HHS*, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002); *Clements v. Secretary of HHS*, No. 95-0484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998). The special masters reason that the NCES represents a major epidemiological study assigning a statistically significant risk of neurological injury for up to seven days following a DPT vaccination. *See, e.g.*, *Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *10; *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *9, n.27; *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *3; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *7. Next, the special masters reason that based predominantly upon the NCES, the IOM determined in 1991 that medical evidence "'is consistent'" at least "'with a causal relation between DPT vaccine and acute encephalopathy, defined in the controlled studies reviewed as encephalopathy, encephalitis, or encephalomyelitis.'" *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *10, citing the 1991 IOM Report at 118; *see also Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *10-12; *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *3; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *8. However, the special masters recognize that in 1991, the IOM deemed medical evidence as "'insufficient'" to establish a causal relation between DPT and "'permanent neurologic'" damage. *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *12, n.34, citing the 1991 IOM Report at 118; *see also Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *3; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *8. Then, the special masters reason that the 1993 NCES Follow-up Study revealed that NCES "case children" exhibited "chronic neurologic dysfunction" at a remarkably higher rate than "non-case children." *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *3 (emphasis omitted); *see also Raj v. Secretary of HHS*, No.96-0294V, 2001 WL 963984 at *8, n.20. Finally, the special masters reason that based upon the 1993 NCES Follow-up Study, the IOM announced in 1994 that medical evidence "'is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within 7 days after receiving DPT vaccine.'" *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *4, citing the 1994 IOM Report at 15 (emphasis omitted); *see also Terran v. Secretary of HHS,* No. 95-0451V, 1998 WL 55290 at *12; *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *12; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *8. The special masters interpret the term "'serious acute neurologic illness'" as "any one of the five neurologic events suffered by case children under the NCES." *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *9; *see also Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *12; *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *13; *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *15, n.12. Thus, the special masters conclude that if a petitioner demonstrates that: (1) a previously neurologically-intact infant entered the hospital with a condition that would have prompted notification to the NCES; (2) the onset of the infant's condition requiring hospitalization occurred within seven days after a DPT vaccination; (3) the infant developed chronic neurological dysfunction; and (4) there is no other identifiable cause for the infant's neurological dysfunction, the petitioner establishes that the DPT vaccine caused more likely than not the infant's condition. *See Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *7, 12; *see also Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *12;

Jenkins v. Secretary of HHS, No. 90-3717V, 1999 WL 476255 at *13; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *9. In crafting the test based upon the NCES and associated medical literature, the special masters acknowledge NCES authors' cautionary note about using NCES data to attribute neurological damage to immunization in an individual case. *See, e.g.*, *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *9, n.26, *12, n.34; *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *12, n.11, *14-15. Nevertheless, the special masters distinguish the medical concept of "medical certainty" from the legal concept of "preponderance of the evidence," finding that a petitioner meets the preponderance of the evidence standard when epidemiological evidence shows a relative risk that exceeds two. *See Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *15; *see also Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *8, n.18, citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1321 (9th Cir. 1995).

THE NCES

The NCES is "one study, among others" developed in 1976 to address "widespread public and professional concern over the safety of pertussis immunization." NCES at 80. Aided by various "professional bodies" in Great Britain, including the British Paediatric Association and the Society of British Neurological Surgeons, a "Research Team" devised the NCES as a case-control method "to assess the risks of certain serious neurological disorders associated with immunization in early childhood and to identify factors that might cause or predispose to such disorders." *Id.*; *see also* NCES at 96-97. "The case-control approach involves the collection of a series of individuals with a particular disease and comparing their history of exposure to the suspected agent with that of an appropriately selected group of individuals who do not have the disease." NCES at 97. The method "has the advantage of simplicity and speed." *Id.*

NCES authors were "concerned primarily with cases of acute neurological illnesses which could result in permanent brain damage or death." NCES at 101. In deciding which illnesses to consider in the NCES, NCES authors recognized that their characterization of the illnesses "needed to be sufficiently broad to capture all" potential study subjects "without producing overwhelming numbers" leading to "an unmanageable burden." *Id.* Based upon "discussions between the Study team and interested paediatricians, neurologists and epidemiologists," NCES authors established "criteria" for "[a] list" of "conditions" covered by the NCES. *Id.* The conditions were: acute or subacute encephalitis/encephalomyelitis/encephalopathy; unexplained loss of consciousness; convulsions with a total duration of more than about ½ hour, *or* followed by coma lasting 2 hours or more, *or* followed by paralysis, or other neurological signs not previously present, lasting 24 hours or more; infantile spasms or West's syndrome; and Reye's syndrome or acute encephalopathy with abnormal liver function tests. NCES at 157. Likewise, NCES authors established a list of conditions excluded from the NCES. The conditions were: confirmed toxic, bacterial, metabolic, neoplastic or traumatic neurological disorders; uncomplicated convulsions, or a series of convulsions lasting less than about ½ hour; and viral or aseptic meningitis *without* encephalopathy. *Id.*

To identify a study population, NCES authors initiated "a national notification system." NCES at 101. NCES authors assumed "that children with serious neurological disorders, particularly those severe enough to result in lasting damage to the child, would be admitted to hospital under the care of paediatricians, infectious disease physicians or neurosurgeons." *Id.* In addition, NCES authors assumed "that children were unlikely to receive primary immunization with pertussis vaccine outside the ages of 2 to 36 months." *Id.* Thus, NCES authors requested each doctor participating in the NCES "to report as soon as possible any child" between the age of two months and 36 months "admitted" to the hospital "under his care" during the study period, July 1, 1976 to June 30, 1979, "who satisfied the specified criteria" for conditions covered by the NCES. *Id.* NCES guidelines encouraged each doctor participating in the NCES to report a child if the doctor harbored any "doubt" about whether the child had sustained a condition covered by the NCES. NCES at 157. Over the course of the study, NCES authors learned "[o]ccaisionally" about potential study subjects from other sources, NCES at 102, such as, apparently, death certificates provided by the British Office of Population Censuses and Surveys. *See* NCES at 106, 144-45.

When a doctor participating in the NCES reported a child to NCES authors, the authors confirmed that "the case appeared to satisfy the Study criteria." NCES at 102. If NCES authors deemed initially a case "to satisfy the Study criteria," the authors asked the reporting "consultant" to complete "a clinical questionnaire" regarding "the child's past history," the child's "clinical condition on admission" to the hospital, "the results of investigations and the clinical progress or condition of the patient at discharge or 15 days after admission, which-ever was the sooner." *Id.* Based upon information in the "clinical questionnaire," NCES authors confirmed again apparently that the case satisfied NCES criteria. *See* NCES at 161. If NCES authors determined that the case satisfied NCES criteria, the authors "accepted" the case into the NCES. NCES at 161. Then, the authors "matched closely" according to gender and age each case accepted into the NCES with two "control children from the local community." NCES at 105. NCES authors conducted a comprehensive investigation of each case accepted into the NCES and of both controls. Through correspondence, and through home interviews, the authors obtained full medical histories, including immunization dates, for all children. *See* NCES at 161; *see also* NCES at 102, 105-106.

Recognizing that the "date of onset" of an NCES condition was "the critical date for the analysis of any relationship to immunization," NCES authors "assigned a date of onset" of the NCES condition for each case accepted into the NCES. NCES at 102. However, the authors discovered that a central assumption--that "the interval from onset" of the NCES condition "to admission" into the hospital "would usually be short"--was "not always justified by events." *Id.* The authors explained that "[i]n some children[,] the onset of neurological illness ultimately leading to brain damage can be insidious and its course only slowly progressive," delaying "considerably" admission into a hospital. *Id.* Thus, NCES authors "decided" to have "an epidemiologist and a paediatrician member of the Study team" ascertain from "*all* available information" a date of onset of the NCES condition for each case accepted into the NCES. *Id.* (emphasis in original). The date of onset of illness was "*the date on which acute neurological symptoms or signs related to the current illness first developed.*" *Id.* (emphasis in original). Nevertheless, at times, NCES authors could not determine an "exact date of onset" for each case accepted into the NCES. *Id.* Therefore, NCES

authors "decided also to analyse the results using the date of the child's admission to hospital, a date which is usually undisputed." *Id.* at 102-03. NCES authors used a particular method to determine the date of onset of the NCES illness in each case "notified after severe convulsions" where "the child had had any earlier convulsion." NCES at 147. According to NCES authors:

> When a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration, for the purpose of the Study the *date of onset of illness* was taken to be the *date of the first convulsion*. However, where a child had a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation, the date of onset of that child's illness was regarded as the date of the major convulsion for which the child was admitted to hospital and notified to the Study.

Id.

In addition, NCES authors classified each case accepted into the NCES based upon the child's apparent condition before the onset of the NCES condition and after the onset of the NCES condition. *See* NCES at 103, 107-08. NCES authors "distinguished" three categories:

> The *first* group were apparently neurologically normal before their illness and also apparently neurologically normal at fifteen days after admission to hospital, or at discharge, whichever was earlier. The *second* group were apparently neurologically normal before their illness, but had a continuing neurological abnormality at fifteen days after admission, or at discharge. The *third* group were neurologically abnormal both before their illness, and at fifteen days after their admission, or at discharge.

NCES at 107-08 (emphasis in original). If a child "*died* in hospital," or if a child exhibited "[a]t *15 days after admission or (if sooner) at discharge*" an "abnormal level of consciousness; [b]ehaviour change causing problems; [p]ersistent motor abnormalities; [p]ersistent cranial nerve dysfunction; [or] [e]vidence of developmental retardation which had either developed for the first time or deteriorated during [the] admission," NCES authors regarded the child to exhibit a "continuing neurological abnormality." NCES at 108. Although NCES authors monitored for at least one year the child's neurological condition in each case accepted into the NCES, *see* NCES at 103-04, the authors employed "the '15-day' assessment" as "a reasonable working classification," believing that few cases would "migrate from one category to another." NCES at 108.

NCES authors accepted approximately 1,180 cases into the NCES. NCES at 107. However, the authors reported only results from "the first 1000 cases accepted" into the NCES because "relevant data" for all cases "were not complete." *Id.* The authors "compared" cases accepted into the NCES and all controls "in relation to their history of immunization with (a) diphtheria/tetanus/pertussis vaccine (with or without oral polio vaccine); (b) diphtheria/tetanus vaccine (with or without oral polio vaccine); and (c) measles vaccine, at a series of intervals before different defined reference dates." NCES at 117. The authors used "two reference dates" for cases:

"the date of hospital admission and the date of onset of the relevant illness." *Id.*; *see also* NCES at 102-03. The authors used one reference date for controls: "the date on which the control child was exactly the same age as the corresponding index child on either day of its admission or the estimated day of onset of illness." NCES at 118. The authors "arbitrarily confined" their comparison of immunization histories to "28 days before admission or onset of illnesses in cases with that in controls." NCES at 146.

NCES authors found that "significantly more cases than controls were immunized with DTP within the 72 hours prior to both the date of admission and the estimated date of onset of their illness." NCES at 118; *see also* NCES at 142. The authors found also that "[t]here were similar but smaller differences between cases and controls for the interval between 72 hours and 7 days." NCES at 118. The authors "emphasised" that because they conducted their analysis "*without* exclusion of cases in which there [was] evidence of another possible cause," NCES at 141 (emphasis in original), their "conservative approach may have had the effect of overestimating the risk rates." NCES at 144; *see also* NCES at 141. In defense of their "rigorous approach" that "eschew[ed] clinical judgement concerning the probable cause in individual cases," NCES at 141, the authors postulated that the vaccine could act "as a 'trigger' in children who would not otherwise have developed a serious neurological illness or that the alternative 'explanation' was itself a chance irrelevant finding." NCES at 143. Thus, while the authors were not able to "show that children with serious vaccine-associated illnesses had any distinctive clinical syndrome which would distinguish them from those whose illness was not vaccine-associated," NCES at 142, the authors concluded nevertheless "that on the balance of the available evidence, DTP vaccine probably can cause acute neurological reactions." NCES at 141.

BACKGROUND

When she became pregnant with Molly, Ms. Moberly was an experienced mother with two children. *See* Pet. ex. 1 at 5A. Ms. Moberly received routine prenatal medical attention during her pregnancy with Molly. *See generally* Pet. ex. 1. Ms. Moberly did not encounter any significant complications with the pregnancy. *See generally* Pet. ex. 1.

Molly was born at 3:03 p.m., on May 17, 1996, at Saint Elizabeth Community Health Center in Lincoln, Nebraska. Pet. ex. 7 at 31. She weighed six pounds, 11 ounces. Pet. ex. 7 at 1. She measured 19¼ inches long. *Id.* Her head circumference was 13¼ inches. *Id.* Her APGAR scores were eight at one minute and nine at five minutes.[9] *Id.*

[9] An APGAR score is a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1498 (27th ed. 1988).

An attending physician evaluated Molly in the newborn nursery on May 18, 1996. *See* Pet. ex. 7 at 1. The attending physician described Molly as "healthy." Pet. ex. 7 at 1. The attending physician anticipated "routine care." *Id.*

An attending physician evaluated Molly in the newborn nursery on May 19, 1996. *See* Pet. ex. 7 at 1. The attending physician noted that Molly was "feeding fine." Pet. ex. 7 at 1. The attending physician described the remainder of Molly's "exam" as "stable." *Id.* The attending physician authorized Molly's discharge from the hospital. *See id.* Before her discharge from the hospital on May 19, 1996, Molly received a hepatitis B vaccination. *See id.*

As an infant, Molly received routine pediatric medical attention from physicians at Auburn Family Health Center in Auburn, Nebraska. *See generally* Pet. ex. 12. Molly experienced typical childhood ailments, such as upper respiratory illnesses and impetigo. *See, e.g.*, Pet. ex. 12 at 4-5. In addition, Molly exhibited possible "reflux," characterized by frequent "spitting up." Pet. ex. 12 at 5; *see also* Pet. ex. 12 at 4. Nevertheless, Molly's growth and development were "normal." *See, e.g.*, Pet. ex. 12 at 5. Molly received her first Tetramune vaccination,[10] her first oral polio vaccine (OPV) and her second hepatitis B vaccination on July 17, 1996, at age two months. Pet. ex. 9 at 8. Molly received her second DPT vaccination and her second OPV on September 17, 1996, at age four months. *Id.*

During the early morning on September 19, 1996, Molly exhibited a "rectal" temperature of 101° Fahrenheit. Pet. ex. 16 at 1; *see also* Pet. ex. 9 at 3; Pet. ex. 17 at 10. Ms. Moberly administered "Tylenol." Pet. ex. 16 at 1. At approximately 2:30 a.m. on September 19, 1996, Molly suffered two seizures. *See* Pet. ex. 16 at 1; *see also* Pet. ex. 3 at 5; Pet. ex. 5 at 1; Pet. ex. 12 at 14; Pet. ex. 17 at 10. The seizures involved apparently "hard tonic-clonic jerking," a "staring look" and "drooling." Pet. ex. 5 at 1. Ms. Moberly telephoned "the hospital" later in the morning on September 19, 1996. Pet. ex. 12 at 14. After speaking with medical personnel at the hospital, Ms. Moberly "elected to have" one of Molly's physicians return the telephone call when the physician arrived at the hospital for "rounds." *Id.*

Molly presented to Auburn Family Health Center on September 20, 1996, for an evaluation of "vomiting, convulsions," lethargy and "fever." Pet. ex. 12 at 6. Molly's temperature was 97.3° Fahrenheit. *Id.* Upon examination, Molly "was quite active." *Id.* The physician observed "some purulent drainage from [Molly's] nose." *Id.* The physician diagnosed an "U[pper]R[espiratory]I[llness]." *Id.* The physician prescribed a ten-day course of an antibiotic. *Id.*; *see also* Pet. ex. 17 at 10.

On October 6, 1996, Molly presented to the Emergency Department at Children's Mercy Hospital in Kansas City, Missouri. *See* Pet. ex 2 at 5. Ms. Moberly reported that at 2:30 a.m., Molly

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[10] Tetramune is a vaccine comprised of diphtheria toxoid, tetanus toxoid, pertussis vaccine and haemophilus b conjugate vaccine. For purposes of this decision, the special master will refer to Tetramune as "DPT."

exhibited "jerking" on her "l[eft] side" for "[two] minutes," accompanied by "staring," lethargy and "drooling." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 7. According to Ms. Moberly, Molly was "very active" after the "episode." Pet. ex. 2 at 5. In addition, Ms. Moberly reported that at 5:30 a.m., Molly exhibited a "similar episode" on her "r[ight] side." *Id.*; *see also* Pet. ex. 2 at 7. Nursing personnel characterized Molly as "alert" and "playful" in the Emergency Department. Pet. ex. 2 at 7. A physician determined that Molly's neurological examination was normal. Pet. ex. 2 at 5. The physician considered a diagnosis of the "possible new onset" of a seizure disorder or "reflux." *Id.* The physician recommended an "elective head C[omputed]T[omography]." *Id.*

Molly underwent a "non-enhanced and enhanced CT scan of the head" on October 7, 1996, at Children's Mercy Hospital. Pet. ex. 2 at 9. The result was "negative." *Id.* A physician suggested "a referral for [an] E[lectro]E[ncephalo]G[ram]" and for the "evaluation of gastro-esophageal reflux." Pet. ex. 2 at 3; *see also* Pet. ex. 12 at 6.

On October 9, 1996, Ms. Moberly telephoned Auburn Family Health Center to schedule an EEG. *See* Pet. ex. 12 at 6. A physician arranged a neurological consultation for Molly with Richard Torkelson, M.D. (Dr. Torkelson). *See id.* The physician believed that Molly's "possible reflux" would "also be evaluated." *Id.*

Dr. Torkelson, Director of University Epilepsy Services at the University of Nebraska Medical Center, examined Molly on October 10, 1996. *See* Pet. ex. 5 at 1. Dr. Torkelson reviewed Molly's medical history, noting "hemi-convulsions" that occurred "about two days" after "an immunization" in September 1996, and again in early October 1996, without "evidence for lateralized change in function." Pet. ex. 5 at 1-2. According to Dr. Torkelson, a thorough assessment of Molly's "systems was just totally unremarkable." Pet. ex. 5 at 1. Dr. Torkelson depicted Molly as a "very interactive" child who "would socially smile quite quickly to even slight cues." Pet. ex. 5 at 2. Dr. Torkelson characterized Molly's "[e]ye movements" as "very good for age," with "excellent fixation and following." *Id.* Dr. Torkelson characterized Molly's "[r]eflexes" as "easily at the 2+ and symmetric level." *Id.* Dr. Torkelson characterized Molly's "traction responses" as "excellent" and "likewise symmetric." *Id.* Dr. Torkelson characterized Molly's "[s]ensation" as "intact throughout to light touch." *Id.* Dr. Torkelson deemed Molly's "sounds" to be "of normal pitch." *Id.* Dr. Torkelson commented that an EEG performed "prior to the visit" appeared "totally normal" in both "the awake and sleeps [sic] states." Pet. ex. 5 at 3; *see also* Pet. ex. 12 at 36. Dr. Torkelson discounted Molly's "reflux," describing Molly's "abundant spitting" as "salivary and not gastric." Pet. ex. 5 at 3. Indeed, Dr. Torkelson offered that Molly looked "so healthy" that he was "inclined to" consider Molly's seizures "as a transient disturbance." *Id.* Thus, Dr. Torkelson advised only observation. *Id.*; *see also* Pet. ex. 12 at 7.

On October 22, 1996, Ms. Moberly telephoned Auburn Family Health Center to discuss Molly's progress. *See* Pet. ex. 12 at 7. Ms. Moberly related that Molly was growing "well." Pet. ex. 12 at 7. However, Ms. Moberly reported that Molly continued to "spit up" often "during the day." *Id.* The physician reviewed treatment "options" with Ms. Moberly. *Id.* In addition, Ms.

Moberly reported that she captured on "tape" one of Molly's episodes comprised of a "twisting" of the "arm" and "a blank stare." *Id.* Ms. Moberly planned to send the tape to Dr. Torkelson. *Id.*

Molly presented to Auburn Family Health Center on October 24, 1996, for evaluation of "persistent congestion with sneezing." Pet. ex. 12 at 7. Ms. Moberly indicated apparently that she had not observed "further seizure activity" since recording one of Molly's episodes on tape. *Id.* Upon examination, Molly exhibited "yellow nasal discharge." *Id.* The physician diagnosed "[p]urulent URI." *Id.* The physician prescribed "Amoxicillin." *Id.* In addition, the physician suggested the use of a "vaporizer and bulb suction if needed." *Id.* The physician decided specifically to avoid "decongestants/antihistamines" pending a determination of "the cause of [Molly's] possible seizures." *Id.* The physician commented that Molly's seizures "began two days after Molly[']s second set of immunizations." *Id.*

Following Molly's October 24, 1996 examination, Ms. Moberly spoke "with the State Health Department." Pet. ex. 12 at 8. Ms. Moberly telephoned Auburn Family Health Center to recount the conversation. *See id.* Ms. Moberly related that medical personnel "felt that [Molly's] seizures could possibly be a reaction to a DPT." Pet. ex. 12 at 8. In addition, Ms. Moberly related that medical personnel recommended that Molly receive "only" the "D[iphtheria]T[etanus]" vaccination "in the future." *Id.*

On October 24, 1996, Jere Gravatt (Ms. Gravatt), a registered nurse practicing at the Nemaha County Health Department, in Auburn, Nebraska, completed a Vaccine Adverse Event Reporting System (VAERS) form regarding Molly's seizures. *See* Pet. ex. 16 at 1.

Between October 24, 1996, and November 4, 1996, Molly suffered several more seizures. *See, e.g.*, Pet. ex. 12 at 7-8. One seizure "was quite long," lasting "at least 12 minutes." Pet. ex. 5 at 4. The seizure "involved the left leg and arm," as well as, "at times, even the left upper eyelid." *Id.* During the seizure, Molly "was able to look about," despite showing "some gaze preference toward the left." *Id.* After the seizure, Molly "had weakness on the left." *Id.* In addition, Molly "went into a deep sleep." *Id.* However, upon arousal, Molly demonstrated "no focal abnormalities." *Id.*

On November 4, 1996, Molly underwent a magnetic resonance imaging (MRI) study. *See* Pet. ex. 5 at 4. Then, Molly presented to Dr. Torkelson. *See* Pet. ex. 5 at 4. According to Dr. Torkelson, Molly's MRI "was totally normal." Pet. ex. 5 at 4. Thus, Dr. Torkelson could "conclude" only that Molly had "independent left and right cortical origins for focal motor seizures with no definable structural abnormality." *Id.* Dr. Torkelson acknowledged that Molly's "parents" were "understandably concerned" that Molly's seizures were "related to the DPT immunization" that Molly received on September 17, 1996. *Id.* However, Dr. Torkelson stated that Molly's clinical condition "would not fall within any of the recognized syndromes that 'may' be related to pertussis." *Id.*

Although Dr. Torkelson lacked "an established etiology" for Molly's condition, he determined to "progress with treatment." Pet. ex. 5 at 4. Dr. Torkelson prescribed "Tegretol suspension." *Id.* Dr. Torkelson noted that if Molly's seizures were "somewhat driven by fevers," as Ms. Moberly suspected, Tegretol would "not really help at all." Pet. ex. 5 at 4-5. Dr. Torkelson identified the "two logical" alternative medications as "phenobarbital or Depakote." Pet. ex. 5 at 5. Regardless, in Dr. Torkelson's view, Molly had "very good odds of outgrowing" her seizures. *Id.*

By November 7, 1996, Molly had "been seizure free for over one w[ee]k." Pet. ex. 12 at 8. During an examination at Auburn Family Health Center, Molly was "acting well." *Id.* Her neurological examination was "normal." *Id.* Thus, Ms. Moberly "elected" to defer the "initiation of the Tegretol." *Id.* The physician agreed with Ms. Moberly's decision. *See id.* However, the physician cautioned that if Molly experienced "a recurrent seizure or prolonged seizure," Molly would have to "start the Tegretol per Dr. Torkelson." *Id.*

On November 13, 1996, Molly presented to the Nemaha County Hospital Emergency Room "with an increasing barking cough for 48 hours." Pet. ex. 4 at 11. Following "nebulizer treatment," medical personnel placed Molly in a "croup tent." *Id.* Molly responded well enough to be "dismissed home" after several hours. *Id.* Molly did not experience "any seizures" associated with her "[l]aryngotracheobronchitis." *Id.*

In mid-December 1996 and in late-January 1997, Molly suffered a couple of upper respiratory illnesses. *See* Pet. ex. 12 at 9. In addition, Molly continued "spitting up" frequently "after meals," creating "quite a mess on her clothes." Pet. ex. 12 at 9. Nevertheless, Molly "remained absolutely seizure free for 12 weeks." Pet. ex. 5 at 7.

On January 22, 1997, Molly experienced a "7- to 10-minute seizure," associated with "a fever of 101 degrees," Pet. ex. 5 at 7; *see also* Pet. ex. 17 at 18, and "croup." Pet. ex. 17 at 18. The seizure "started with her right arm, then involved her right arm and leg." Pet. ex. 5 at 7. Molly exhibited "slight perioral cyanosis" toward "the very end of the seizure." *Id.* However, Molly "did not seem to have any deficit following the seizure, such as a mild right hemiparesis." *Id.* Ms. Moberly and Dr. Torkelson "had a long discussion over the phone" about Molly's seizure. *Id.* Ms. Moberly indicated apparently that she preferred "intermittent therapy" for Molly's seizures if the seizures stayed "infrequent." *Id.* Dr. Torkelson suggested "Valium." *Id.* Ms. Moberly scheduled an appointment to obtain Valium from Dr. Torkelson and "to go over its use." *Id.*

Dr. Torkelson examined Molly on January 27, 1997. *See* Pet. ex. 5 at 7. Dr. Torkelson noted that Molly showed "a significant acceleration" in weight. Pet. ex. 5 at 7. According to Dr. Torkelson, Molly was "alert and very visually interactive." *Id.* Dr. Torkelson observed that Molly's "fine movements of" the "extremities" were "equal bilaterally." *Id.* Dr. Torkelson observed "excellent strength and tone bilaterally." *Id.* Dr. Torkelson described Molly's "developmental milestones" as "easily age appropriate." *Id.* Dr. Torkelson elaborated that Molly pulled "well to sitting" and had "good support," with "no head lag." *Id.*

Dr. Torkelson reviewed the prescription for Valium with Ms. Moberly. *See* Pet. ex. 5 at 7. Dr. Torkelson commented that were Molly to "have a seizure very soon," he "would then rethink" his advice regarding "chronic medications." Pet. ex. 5 at 7. Dr. Torkelson added that he "would favor Depakote followed by phenobarbital" if subsequent seizures appeared "again precipitated by a fever." *Id.*

Dr. Torkelson diagnosed again "simple partial (motor) seizures, alternating in side." Pet. ex. 5 at 8. Although Dr. Torkelson indicated that there exists "a disorder that is alternating hemiconvulsions in childhood," Dr. Torkelson stated that he did not "have sufficient data" to render a firm conclusion. *Id.* Dr. Torkelson recommended another evaluation "in around six months' time." Pet. ex. 5 at 7.

Molly's seizures recurred. *See, e.g.*, Pet. ex. 12 at 10. At some point, Dr. Torkelson instituted Tegretol. *See* Pet. ex. 12 at 10. By February 19, 1997, Dr. Torkelson decided to place Molly on Depakote, while "tapering off of Tegretol." Pet. ex. 12 at 10.

Molly presented to Auburn Family Health Center on February 19, 1997, for her nine-month well-child examination. *See* Pet. ex. 12 at 10. She weighed 18 pounds, five ounces. Pet. ex. 12 at 10. She measured 28 inches long. *Id.* Her head circumference was 17½ inches. *Id.* Molly was "alert and active," although she appeared to "have some photophobia with the bright light." *Id.* The physician noted that Molly was "sitting unassisted." *Id.* In addition, the physician noted that Molly was "starting to pull herself up around furniture and walk and crawl." *Id.* Molly received a DT vaccination and a third hepatitis B vaccination. *Id.* The physician recommended routine medical attention "as warranted." *Id.*

Molly experienced a seizure in "the afternoon" following her February 19, 1997 DT vaccination. Pet. ex. 9 at 3. Molly experienced other seizures in late February 1997 and in March 1997. *See, e.g.*, Pet. ex. 12 at 11-12. In addition, Molly suffered several upper respiratory illnesses accompanied by fever and congestion. *See, e.g.*, Pet. ex. 12 at 11-12.

On April 1, 1997, Christopher J. Harrison, M.D. (Dr. Harrison), Associate Professor of Pediatrics in the Division of Pediatric Infectious Diseases at Children's Hospital, Creighton University, and Alice Pong, M.D. (Dr. Pong), Pediatric Infectious Disease Fellow in the Division of Pediatric Infectious Diseases at Childrens Hospital, Creighton University, evaluated Molly. *See* Pet. ex. 9 at 3. Dr. Harrison and Dr. Pong reviewed Molly's medical history. *See* Pet. ex. 9 at 3. They noted that Molly's most recent seizure had occurred on March 10, 1997. *See* Pet. ex. 9 at 3. According to Dr. Harrison and Dr. Pong, Molly's "[n]eurological examination" was "normal." Pet. ex. 9 at 4. Indeed, Dr. Harrison and Dr. Pong said that Molly was "doing well from a developmental standpoint." Pet. ex. 9 at 3. They indicated that Molly was "pulling to stand and babbling." *Id.*

Dr. Harrison and Dr. Pong considered the "etiology" of Molly's condition to be "unclear." Pet. ex. 9 at 4. They recognized that Molly's initial seizure was "temporally related to" a DPT vaccination. *Id.* In addition, they recognized that another of Molly's seizures was "temporally

related to" a DT vaccination. *Id.* Nevertheless, they concluded that they could not prove "[c]ausality." *Id.* They commented that the "association between the DT and seizure activity is even more unclear, especially since [Molly] may have had a concomitant febrile illness at the time and was in transition with her anticonvulsive medication." *Id.* However, they acknowledged "the possibility that the DPT may have provoked an underlying convulsive condition." *Id.*

Dr. Harrison and Dr. Pong recommended "limiting" Molly's "next booster" vaccination "to the tetanus (T) component only" in order "to minimize the possibility of future events." Pet. ex. 9 at 4. However, they suggested that Molly receive "her M[easles]M[umps]R[ubella immunization] and other vaccines at the usual time." *Id.* They hoped that "the nature of Molly's seizure disorder" would become "more clear" as Molly matured so that they could address "future immunizations with diphtheria vaccine and/or acellular pertussis vaccine." *Id.*

For the remainder of April 1997 and into early May 1997, Molly appeared relatively stable. *See, e.g.*, Pet. ex. 12 at 12-13; Pet. ex. 17 at 24. Beginning on May 11, 1997, Molly was "out of sorts." Pet. ex. 12 at 13. She had "congestion with fever." *Id.* She missed several doses of "her Depakote." *Id.* On May 13, 1997, she experienced a "breakthrough seizure secondary to fever and decreased intake of" anticonvulsant medication. *Id.* In addition, on May 13, 1997, a physician at Auburn Family Health Center observed "full" otitis media in Molly's right ear. *Id.* The physician prescribed an antibiotic for "ten full days." *Id.* The physician recommended also "methods to increase [Molly's] oral intake of" anticonvulsant medication. *Id.*

At 12:57 p.m., on May 26, 1997, Molly arrived by ambulance at the Skaggs Community Health Center Emergency Department in Branson, Missouri. Pet. ex. 15 at 2. She was exhibiting "tic-like activity of the extremities." *Id.* By report, Molly had suffered a "prolonged seizure," Pet. ex. 15 at 3, lasting perhaps one hour. *See* Pet. ex. 21 at 4. A physician diagnosed otitis media, as well. Pet. ex. 15 at 3. Medical personnel observed Molly throughout the afternoon. *See, e.g.*, Pet. ex. 15 at 2. At one point, medical personnel described Molly as "extremely irritable" yet "consoleable [sic]." Pet. ex. 15 at 2. Although Molly refused initially "to eat or nurse," Molly consumed eventually a "sm[all] am[oun]t of orange juice & banana." *Id.* After several hours, medical personnel released Molly from the Emergency Department. *See id.* Medical personnel advised Ms. Moberly to "return to" the Emergency Department if Molly had "further problems." Pet. ex. 15 at 2.

Molly continued to experience "persistent acute otitis media" and "fever" into late June 1997. Pet. ex. 12 at 15; *see also* Pet. ex. 12 at 14. According to a physician at Auburn Family Health Center, Molly suffered also a "mild exacerbation" of her seizures "secondary to her fevers." Pet. ex. 12 at 15. On June 22, 1997, Molly presented to the Nemaha County Hospital Emergency Room. *See* Pet. ex. 3. Ms. Moberly reported that Molly had exhibited "fevers to 105 degrees" Fahrenheit. Pet. ex. 3 at 3. In addition, Ms. Moberly reported that Molly had experienced four seizures over the course of several days. *See id.*

Molly's temperature in the emergency room was "102 degrees" Fahrenheit. Pet. ex. 3 at 3. The attending physician observed "[r]ight otitis media." *Id.* The attending physician observed also a "profuse amount of clear to slightly greenish discharge" from Molly's "nose." *Id.* The attending physician consulted Dr. Torkelson. *See id.* The attending physician indicated that Dr. Torkelson "felt that [Molly's] seizures were probably aggravated by [Molly's] fevers." Pet. ex. 3 at 3. Thus, the attending physician related that Dr. Torkelson "felt that further evaluation" of Molly's seizures "was unwarranted." *Id.*

Molly returned on June 26, 1997, to Auburn Family Health Center for "follow[-]up" of her "otitis and URI." Pet. ex. 12 at 15. She appeared to have "improved markedly." *Id.* Indeed, the physician commented that Molly was "relaxed and happy." *Id.* During Molly's examination, Ms. Moberly expressed concern "about some developmental delays" because Molly was "not walking." *Id.* The physician described Molly as "very social and interactive." *Id.* In the physician's view, Molly's "ambulation" skills were "W[ithin]N[ormal]L[imits]." Pet. ex. 12 at 16. However, the physician noted that Molly did "not have appreciable speech." Pet. ex. 12 at 15. The physician determined to "monitor" Molly "for evidence of developmental delays." Pet. ex. 12 at 16.

Molly was relatively stable throughout July 1997 and into early August 1997. *See, e.g.*, Pet. ex. 12 at 16. On August 11, 1997, Molly experienced a seizure when she awoke in the morning. *See* Pet. ex. 21 at 9; *see also* Pet. ex. 12 at 17. After Ms. Moberly administered Valium, Molly's seizure "stopped." Pet. ex. 21 at 7. Molly experienced another seizure when her temperature rose about one hour later. *See* Pet. ex. 21 at 9.

Molly was to undergo an MRI on August 11, 1997, at the University of Nebraska Medical Center in Omaha, Nebraska. *See* Pet. ex. 21 at 2; *see also* Pet. ex. 12 at 17. Ms. Moberly and Molly traveled from their home in Auburn, Nebraska, to Omaha, Nebraska, for Molly's MRI. *See, e.g.*, Pet. ex. 12 at 17. However, when Molly presented for her MRI, medical personnel decided to reschedule the MRI because Molly had received Valium. *See, e.g.*, Pet. ex. 21 at 2.

Molly experienced another seizure on August 11, 1997, while Ms. Moberly was driving on a "busy street" to a shopping mall in Omaha, Nebraska. Pet. ex. 21 at 9. Although the "seizure stopped," Molly continued "shaking" and "twitching" at the shopping mall. *Id.* Ms. Moberly administered another dose of Valium. *Id.* Nevertheless, Molly continued "to 'shiver.'" *Id.* In addition, Molly appeared "unresponsive." *Id.*; *see also* Pet. ex. 21 at 7. According to Ms. Moberly, Molly's episode lasted "approximately 45 minutes to one hour." Pet. ex. 21 at 2; *see also* Pet. ex. 12 at 17. Ms. Moberly summoned an ambulance. *See* Pet. ex. 21 at 12; *see also* Pet. ex. 21 at 2, 7, 9.

Molly arrived at the University of Nebraska Medical Center at 2:00 p.m., on August 11, 1997. Pet. ex. 21 at 9. At 2:05 p.m., triage personnel described Molly as "alert" and "awake." Pet. ex. 21 at 10. An emergency room physician "assumed care" of Molly at 3:00 p.m. Pet. ex. 21 at 8. Upon examination, Molly appeared "alert" and "nontoxic." Pet. ex. 21 at 7. She exhibited "good tone of all four extremities." *Id.* However, her "[e]ar drums" were "red." *Id.* At some point, the

emergency room physician administered "Rocephin" for "otitis media." Pet. ex. 21 at 2. The emergency room physician suspected that Molly had suffered "status epilepticus." Pet. ex. 21 at 8. The emergency room physician consulted Dr. Torkelson. *See id.* Dr. Torkelson recommended an MRI. *See id.*

Molly experienced another seizure at 3:40 p.m. *See* Pet. ex. 21 at 8. At 4:16 p.m., Molly underwent an MRI of her brain. *See* Pet. ex. 21 at 28. The MRI was "[n]ormal." Pet. ex. 21 at 28. Molly experienced another seizure at 5:50 p.m. Pet. ex. 21 at 8.

Laboratory results on August 11, 1997, indicated that Molly's "Depakote level" was "subtherapeutic." Pet. ex. 21 at 15. Dr. Torkelson directed the administration of "a bolus of Depakote." Pet. ex. 21 at 2; *see also* Pet. ex. 21 at 11. At 9:10 p.m., the emergency room physician "[a]dmitted" Molly into the hospital "under the care of Dr. Torkelson." Pet. ex. 21 at 8; *see also* Pet. ex. 21 at 23.

Although Molly had experienced as many as six seizures throughout the day on August 11, 1997, Molly did not experience further seizures following admission into the hospital. *See* Pet. ex. 21 at 2. Molly was "slightly more irritable than usual" during the night on August 11, 1997, and into the morning on August 12, 1997. Pet. ex. 21 at 2. In addition, Molly displayed "some rapid breathing overnight." Pet. ex. 21 at 20. Nevertheless, Molly "ate fine and slept fine." Pet. ex. 21 at 2. A physical examination on August 12, 1997, revealed "no focal neurologic deficit." Pet. ex. 21 at 20. Dr. Torkelson decided to discharge Molly on August 12, 1997, with instructions to "follow-up" with her pediatricians at Auburn Family Health Center. Pet. ex. 21 at 2.

On August 29, 1997, Molly presented to Auburn Family Health Center. *See* Pet. ex. 12 at 18. She appeared "bothered by her left ear." Pet. ex. 12 at 18. The physician noted that Molly had endured "a lot of problems with ear infections." *Id.* The physician diagnosed "[l]eft otitis media." *Id.* The physician prescribed an antibiotic. *See id.* The physician commented that Molly was "not walking on her own." Pet. ex. 12 at 18. In addition, the physician commented that although Molly was "bright" and understood "a lot of things," she was "not talking much." *Id.* In mid-September, Molly received a referral to an early intervention program. *See* Pet. ex. 12 at 68.

Molly continued to suffer recurrent fevers, persistent upper respiratory illnesses and frequent seizures throughout September 1997 and October 1997. *See, e.g.* Pet. ex. 12 at 18-20; Pet. ex. 3 at 4. An "allergy eval[uation]" was "basically" normal. Pet. ex. 12 at 21. An investigation involving sinus cultures to identify "a resistant pathogen" was normal. Pet. ex. 3 at 9; *see also* Pet. ex. 3 at 11; Pet. ex. 12 at 21. In early October 1997, Molly received several vaccinations, including a DT booster. *See* Pet. ex. 12 at 20. By late October 1997, Molly's pediatricians at Auburn Family Health Center planned an "indepth seizure eval[uation] at the Minnesota Seizure Disorder Clinic" for Molly. Pet. ex. 12 at 21.

On November 10, 1997, Molly entered the Epilepsy Unit at Children's Health Care-St. Paul in St. Paul, Minnesota, for four days. *See* Pet. ex. 11 at 3. During Molly's hospitalization, Frank

Ritter, M.D. (Dr. Ritter), hoped to "clarify" Molly's seizure "events," identify a "possible etiology" for Molly's condition and "determine treatment options." Pet. ex. 11 at 2. Dr. Ritter placed Molly on "video EEG monitoring" for a 65-hour period from November 10, 1997, to November 13, 1997. Pet. ex. 11 at 3; *see also* Pet. ex. 11 at 12-19. In addition, Dr. Ritter referred Molly for an occupational therapy consultation and for a speech and language consultation. *See* Pet. ex. 11 at 3-4.

While Molly "was hooked up to video EEG monitoring," she experienced three seizures. Pet. ex. 11 at 3; *see also* Pet. ex. 11 at 15-16. Dr. Ritter depicted two of Molly's seizures as "complex partial seizures manifested only as staring and unresponsiveness lasting between 2-3 minutes each." Pet. ex. 11 at 3. Dr. Ritter depicted one of Molly's seizures as a "secondarily generalized tonic-clonic seizure arising out of sleep." *Id.* According to Dr. Ritter, Molly's EEG "suggest[ed] an area of potential epileptogenesis from the right hemisphere" of Molly's brain, "and possibly from the left." Pet. ex. 11 at 17.

Dr. Ritter stated that Molly's occupational therapy evaluation revealed deficits in both "motor skills" and "[c]ognitive skills." Pet. ex. 11 at 4. Dr. Ritter identified "[m]otor concerns" as "plateaued motor development with even mild regression." *Id.* Dr. Ritter identified cognitive weaknesses as "significantly[-]delayed expressive language skills, moderately[-]delayed imitation skills and mildly[-]delayed problem solving skills." *Id.* Nevertheless, Dr. Ritter said that Molly possessed "many strong skills," including the desire "to move and explore objects." *Id.*

Dr. Ritter stated that Molly's speech and language evaluation revealed deficits in both "receptive language skills" and "expressive language skills." Pet. ex. 11 at 3. Dr. Ritter identified a "possible motor planning component influencing speech development." *Id.* Dr. Ritter noted that Molly's "feeding" and "swallowing" skills were "within normal limits." *Id.*

Dr. Ritter did not discover an etiology for Molly's seizures, although he did discuss with Molly's parents "[t]he issue of immunization." Pet. ex. 11 at 4-5. Dr. Ritter concluded that Molly did "not have symptoms for any progressive disease." Pet. ex. 11 at 5. Nevertheless, Dr. Ritter did not believe that Molly would "outgrow her seizures." Pet. ex. 11 at 4. And, Dr. Ritter could not "predict" easily Molly's "future development." *Id.* Thus, Dr. Ritter wanted "to increase the seizure threshold and decrease seizure spread." *Id.* Dr. Ritter offered that with improved "seizure control," Molly's "potential of course would be much better." *Id.*

Dr. Ritter recommended the trial of "a couple of medications first," followed by other interventions, like a "Ketogenic diet." Pet. ex. 11 at 5. Dr. Ritter characterized "surgery" as a "limited" treatment "option" because Molly's EEG showed "no obvious focus" for Molly's seizures. *Id.* Dr. Ritter did not contemplate "further researching" of Molly's condition. *Id.* Dr. Ritter advised a "followup with Dr. Torkelson." Pet. ex. 11 at 6.

Following her discharge from Children's Health Care-St. Paul, Molly did "quite well." Pet. ex. 12 at 23. Then, on December 31, 1997, Molly exhibited a slight temperature. *See id.* She suffered "six seizures" on December 31, 1997. Pet. ex. 12 at 23.

In early 1998, Molly suffered "break-through seizures about every two to three weeks" as Dr. Ritter attempted to adjust Molly's anticonvulsant medications, including "Topamax." Pet. ex. 22 at 1; *see also* Pet. ex. 12 at 24. Dr. Torkelson evaluated Molly on March 6, 1998. *See* Pet. ex. 22. After reviewing Dr. Ritter's "very extensive and thorough" report, Dr. Torkelson expressed that he "was a little dismayed to learn that [Molly] was having additional subclinical electrical seizures, or, at least seizures with very subtle clinical change, in addition to her larger seizures." Pet. ex. 22 at 1. Dr. Torkelson added he had seen"no indications for" subclinical electrical seizures based upon the "regular electroencephalograms" that he had performed on Molly. *Id.*

Upon examining Molly, Dr. Torkelson described Molly's "growth parameters" as "excellent." Pet. ex. 22 at 1. A "review of systems" revealed "nothing" significant except for "developmental delays." *Id.* Dr. Torkelson commented that Molly appeared "more interactive and social" than she appeared in previous evaluations. *Id.* According to Dr. Torkelson, Ms. Moberly related Molly's "improved" demeanor to the Topamax. *Id.*

Dr. Torkelson diagnosed again "[a]lternating hemiconvulsions." Pet. ex. 22 at 2. However, Dr. Torkelson characterized the seizures as "largely generalized" and "medically intractable." *Id.* In Dr. Torkelson's view, the "etiology" for Molly's condition remained "uncertain." *Id.*

Dr. Torkelson reviewed Molly's medication regimen. *See* Pet. ex. 22 at 2. Dr. Torkelson recommended the eventual elimination of one of Molly's anticonvulsant medications. *See* Pet. ex. 22 at 2. Dr. Torkelson hoped to "achieve control" of Molly's seizures with Topamax alone. *See* Pet. ex. 22 at 2.

Molly's seizures continued. On May 23, 1998, Molly presented to the Nemaha County Hospital Emergency Room "in status epilepticus." Pet. ex. 3 at 18. She was "not breathing." *Id.* She required "intubation." *Id.* Molly's seizure lasted "approximately" one-and-one-quarter hours. Pet. ex. 8 at 8. When Molly was "stable," Pet. ex. 3 at 16, the emergency room physician authorized Molly's transfer by ambulance to Children's Memorial Hospital in Omaha, Nebraska. Pet. ex. 3 at 18. Molly did not experience other seizures after her admission into Children's Memorial Hospital. *See* Pet. ex. 8 at 8. By May 24, 1998, Molly "was stable and was awakened back to her usual self." Pet. ex. 8 at 10. The attending physician "discharged" Molly "to home." *Id.*

Molly's treating physicians encountered significant difficulty in their attempt to control Molly's seizures. *See, e.g.*, Pet. ex. 8 at 8; Pet. ex. 40 at 1-8; Pet. ex. 47 at 3, 6. Molly's treating physicians instituted numerous anticonvulsant medication changes. *See, e.g.*, Pet. ex. 40 at 1-8; Pet. ex. 41 at 5; Pet. ex. 47 at 3, 6. In addition, Molly's treating physicians instituted a Ketogenic diet. *See* Pet. ex. 47 at 6. Nevertheless, Molly's seizures remained "medically refractory." Pet. ex. 50 at 16. At times, Molly's developmental skills appeared to regress as Molly's seizures increased. *See, e.g.*, Pet. ex. 50 at 16-17.

THE MEDICAL EXPERT TESTIMONY

Dr. Kinsbourne[11]

Dr. Kinsbourne opined that Molly's September 17, 1996 DPT vaccination "caused" Molly's current condition, encompassing "epilepsy and impair[ed] mental function." Tr. at 20-21; *see also* Tr. at 9. Dr. Kinsbourne based his opinion upon "both clinical and epidemiological grounds." Tr. at 10. In addition, Dr. Kinsbourne proposed a biological "mechanism" for Molly's condition. Tr. at 18-20; *see also* Tr. at 27, 31-32.

Dr. Kinsbourne reviewed Molly's medical history. Dr. Kinsbourne noted that Molly exhibited "normal development" before September 17, 1996. Tr. at 9. In addition, Dr. Kinsbourne noted that "[w]ithin 24 hours" after she received a DPT vaccination on September 17, 1996, Molly displayed "right and left focal" seizures. *Id.* Dr. Kinsbourne commented that Molly "did have a fever" with "at least one of" her "observed" seizures. *Id.* Further, Dr. Kinsbourne noted that Molly experienced "more seizures" as she matured, including seizures that lasted longer than "30 minutes." Tr. at 10. Dr. Kinsbourne characterized Molly's additional seizures as "basically resistant to treatment." *Id.* Finally, Dr. Kinsbourne noted that Molly "lost mental skills" eventually. *Id.; see also* Tr. at 35.[12]

According to Dr. Kinsbourne, EEG evidence demonstrates that Molly's seizures arise from several areas "distributed over the cortex of the cerebrum," Tr. at 10, reflecting a "damaged brain." Tr. at 11; *see also* Tr. at 21. Dr. Kinsbourne offered that he is "aware of sufficient literature to indicate that the DPT vaccination is capable of causing, on rare occasion, damage" like Molly suffers. Tr. at 11. Dr. Kinsbourne stated that Molly's medical records do not contain "evidence" of "other causation." *Id.* Thus, Dr. Kinsbourne concluded that Molly's condition is consistent clinically with DPT injury. *See id.*; *see also* Tr. at 22-23.

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[11] Dr. Kinsbourne received his medical degree from Oxford University in England. Pet. ex. 33A at 1. He is a Member of the Royal College of Physicians. *Id.* In addition, he is certified by the American Board of Pediatrics. *Id.* He belongs to the American Neurological Association and to the Child Neurology Society. *Id.* at 4. He holds a variety of academic and hospital appointments. *Id.* at 1. He is a full professor at the University of New York, where he teaches "brain organization." Transcript (Tr.) at 8.

[12] Dr. Kinsbourne acknowledged that Molly's medical records do not corroborate Ms. Moberly's affidavit statements that Molly exhibited an immediate, substantial change in her behavior following her initial seizures. *See* Tr. at 23-24, 37, 40-41; Pet. ex. 32. However, Dr. Kinsbourne declared that the reliability of Ms. Moberly's affidavit statements is not "crucial" to his opinion. Tr. at 40-41. Rather, Dr. Kinsbourne indicated simply that if Ms. Moberly's account were true, he would possess a greater "level of certainty" in his opinion. Tr. at 40.

Moreover, in Dr. Kinsbourne's view, the presentation of Molly's condition "meets" the "inclusion criteria" of the NCES, "the only satisfactory epidemiological study" regarding DPT and neurological injury. Tr. at 11. Dr. Kinsbourne asserted that because the NCES exposed "a positive outcome" between DPT and certain neurological injuries within a certain time frame following vaccination, the NCES "would validate" a correlation between Molly's September 17, 1996 DPT vaccination and Molly's current condition. Tr. at 11-12. Dr. Kinsbourne explained his conclusion.

Dr. Kinsbourne indicated essentially that in designing the study, NCES authors crafted a "general rule" to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. Tr. at 12; *see also* Tr. at 42-43. In addition, Dr. Kinsbourne stated that in designing the study, NCES authors crafted also "an exception to the general rule." Tr. at 12; *see also* Tr. at 32, 42-43. Dr. Kinsbourne recited language from the NCES regarding the exception. Tr. at 14.[13] Dr. Kinsbourne related that NCES authors invoked specifically the exception when, in investigating a case child's medical history, they discovered that the child had suffered seizures at any point before the qualifying neurological illness. *See, e.g.*, Tr. at 13. Dr. Kinsbourne elaborated that if NCES authors discovered that a case child had suffered seizures at any point before the qualifying neurological illness, they assessed whether the seizures and the qualifying neurological illness were "apparently caused by the same pathological process" or whether the seizures and the qualifying neurological illness were independent events. Tr. at 13; *see also* Tr. at 42. Dr. Kinsbourne said that if NCES authors considered the seizures and the qualifying neurological illness to share "the same pathological process," they deemed the date of onset of the qualifying neurological illness to be the date "of the first seizure, even though [the first seizure] itself in isolation would not have met" NCES reporting "criteria." Tr. at 13; *see also* Tr. at 42-43.

Dr. Kinsbourne discussed NCES authors' rationale for devising the exception. Quoting the NCES, Dr. Kinsbourne offered that NCES authors "postulated" that DPT might initiate "a series of events," like "one or more short convulsions," that leads "much later to a serious convulsion or to brain damage." Tr. at 14. According to Dr. Kinsbourne, NCES authors intended the exception to capture all possible vaccine-associated cases. *See, e.g.*, *id.*

At the outset, Dr. Kinsbourne recognized that "[t]he wording" of the exception "is not clear." Tr. at 13. Therefore, Dr. Kinsbourne proclaimed that he considered his role in the proceeding to be "pointing out to" the special master "possible interpretations" of the exception. Tr. at 38; *see also* Tr. at 13, 35-36, 38-39, 41-42. Moreover, Dr. Kinsbourne asserted that the "example of progressive deterioration" that NCES authors cited in the exception does not describe "DPT causation." Tr. at 15; *see also* Tr. at 34, 37-38, 41, 43-44. Rather, Dr. Kinsbourne maintained that "progressive mental deterioration is really caused by . . . various well-known syndromes which one would not mistake for DPT injury." Tr. at 15; *see also* Tr. at 17, 34, 37, 39, 41, 43-44. Thus, Dr. Kinsbourne stated that he does not "find" the example that NCES authors cited in the exception to be "helpful." Tr.

[13] "When a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration, for the purpose of the Study the *date of onset of illness* was taken to be the *date of the first convulsion*." NCES at 147 (emphasis in original).

at 34. But, then, Dr. Kinsbourne indicated that "[m]aybe" NCES authors meant the example of progressive deterioration to reflect situations in which a seizure disorder leads to a loss of "mental skills" as the "seizures get worse." Tr. at 35-37; *see also* Tr. at 41-42.

Regardless, Dr. Kinsbourne posited that "progressive mental deterioration" is one extreme "of a spectrum of what in fact can happen after DPT." Tr. at 14-15. Dr. Kinsbourne posited also that "idiopathic epilepsy," defined as "seizures triggered by a variety of different stimuli," is the other extreme "of a spectrum of what in fact can happen after DPT." *Id.*; *see also* Tr. at 25-26, 112. Dr. Kinsbourne advanced that NCES authors intended the exception to express "something in between" the extremes of the spectrum. Tr. at 16; *see also* Tr. at 39. Thus, Dr. Kinsbourne attempted to depict a "clinical picture" that "would reasonably approximate the appearance of a common cause and still be within the arena of what happens" with "DPT." Tr. at 39; *see also* Tr. at 16-17, 37. Dr. Kinsbourne suggested that the clinical picture involves "the same kind of problem happening over a period of time." Tr. at 17.

Dr. Kinsbourne testified that Molly received in May 1997 emergent medical attention for a seizure "in excess of 30 minutes." Tr. at 12; *see also* Tr. at 13. Thus, Dr. Kinsbourne insisted that Molly's May 1997 seizure would have prompted "definitely" notification to the NCES. Tr. at 12. However, Dr. Kinsbourne conceded readily that because Molly's May 1997 seizure occurred months after Molly's September 17, 1996 DPT vaccination, Molly could not derive any benefit from NCES conclusions under the "general rule" that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *Id.*

Nevertheless, Dr. Kinsbourne maintained that "a common pathological process unites" Molly's May 1997 seizure "with" Molly's initial seizures in September 1996. Tr. at 13; *see also* Tr. at 39. In Dr. Kinsbourne's view, Molly exhibited "a particular seizure pattern" that "repeated and repeated and repeated." Tr. at 16-17. According to Dr. Kinsbourne, Molly's seizure pattern did not change "in its nature." Tr. at 17. Thus, Dr. Kinsbourne stated that, under the "subjective criterion set by the text" of the exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES, Tr. at 17, he would "predate" the onset of Molly's condition to Molly's first seizure in September 1996. Tr. at 13. Indeed, Dr. Kinsbourne pronounced that he cannot "think of a type of clinical picture much different from" Molly's clinical picture that would qualify under the exception. Tr. at 37; *see also* Tr. at 17. Dr. Kinsbourne noted that Molly's first seizure in September 1996 occurred "within" the "time frame" following "DPT vaccination" cited as statistically significant by NCES authors. Tr. at 13. Therefore, Dr. Kinsbourne urged that critical NCES statistical conclusions apply to Molly. *Id.*

Dr. Kinsbourne reviewed "a position" regarding a "mechanism of damage" that he developed with John Menkes, M.D. (Dr. Menkes). Tr. at 18-19; *see also* Tr. at 26-32. Dr. Kinsbourne stated that the "whole cell [pertussis] vaccine contains several toxins," including "two" toxins "that most people credit with major importance:" "pertussis toxin" and "endotoxin." Tr. at 18. Dr. Kinsbourne said that the medical community does not dispute that the pertussis toxin is "neurotoxic." *Id.*; *see*

also Tr. at 29. In addition, Dr. Kinsbourne said that the medical community does not dispute that endotoxin is "capable of increasing the permeability of the walls of blood vessels." Tr. at 19.

According to Dr. Kinsbourne, the medical community has "known for years" that pertussis toxin "is capable of binding to the surface of neurons," particularly "a potent complex called the G proteins." Tr. at 18; *see also* Tr. at 28. Dr. Kinsbourne characterized G proteins as "instrumental in facilitating" the "signaling" of "information" between neurons. Tr. at 18. Dr. Kinsbourne added that the G protein "system" is adept at controlling "inhibitor influences from one neuron to the next." *Id.* Dr. Kinsbourne explained that when pertussis toxin attaches to G proteins, the toxin "inactivates those proteins," creating "a deficiency of inhibition." *Id.* Dr. Kinsbourne elaborated that the "deficiency of inhibition" leads "to a net surplus of excitation which is capable of damaging the cell by having it fire too much or die." Tr. at 18-19.

Dr. Kinsbourne indicated that "in normal circumstances," the pertussis toxin is not able to bind to G proteins because the pertussis toxin "doesn't gain access to the brain." Tr. at 19; *see also* Tr. at 28. However, Dr. Kinsbourne testified that he and Dr. Menkes believe that the effect of endotoxin on "those blood vessels which are proximate to the brain" allows occasionally pertussis toxin to breach "the blood brain barrier," causing neurological damage. Tr. at 19; *see also* Tr. at 26-27. Dr. Kinsbourne remarked that based upon the theory, he and Dr. Menkes became "strong proponents" of an "acellular [pertussis] vaccine" with little or no endotoxin. Tr. at 19-20; *see also* Tr. at 30.

Dr. Kinsbourne agreed that the theory has not been tested. Tr. at 27; *see also* Tr. at 29. Nevertheless, Dr. Kinsbourne maintained that many "steps" in the theory "are known to be the case." Tr. at 28. Moreover, Dr. Kinsbourne asserted that the decrease in "serious neurological events" following the introduction in 1996 of an acellular pertussis vaccine provides "some validation" of the theory. Tr. at 19-20; *see also* Tr. at 30. Regardless, Dr. Kinsbourne conceded that the record does not contain "[lab]oratory findings" or "physiological findings" that support the application of the theory in Molly's case. Tr. at 32.

Dr. Baumann[14]

Dr. Baumann opined that "[t]here's not a relationship between" Molly's September 17, 1996 DPT vaccination and Molly's "illness." Tr. at 47; *see also* Tr. at 50, 63. In Dr. Baumann's view, Molly did not exhibit "any evidence of an acute severe neurologic injury" following her initial seizures in September 1996. Tr. at 47; *see also* Tr. at 48-49, 51-52, 55, 63, 87, 104. Although Dr. Baumann acceded that all of Molly's seizures are "related," Tr. at 57-58; *see also* Tr. at 75-76, 99, Dr. Baumann insisted that the course of Molly's seizure disorder does not reflect a single pathological process, as contemplated by the exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *See* Tr. at 50, 55-57, 71-75, 98-99, 101, 103-05. Rather, Dr. Baumann maintained that Molly suffers "idiopathic epilepsy." Tr. at 50; *see also* Tr. at 73, 101, 108. Moreover, Dr. Baumann contended that the "confidence intervals" in the NCES are so "large" that the "numbers" may not be valid. Tr. at 62-63. Finally, Dr. Baumann critiqued Dr. Kinsbourne's and Dr. Menkes's theory on the biological mechanism of DPT injury. Tr. at 94-95.

Dr. Baumann testified that NCES authors attempted to "define" cases of "acute neurologic injury" that they believed "to have a relationship to chronic neurologic injury." Tr. at 53; *see also* Tr. at 58-59, 65-66. In addition, Dr. Baumann testified that NCES authors attempted to devise a method to "date" the "onset" of the acute neurological injury in the cases. Tr. at 53. Dr. Baumann explained that NCES authors needed to "count days" between the administration of a DPT vaccination and the onset of an acute neurological injury in cases "vis a vis controls." *Id.*; *see also* Tr. at 64.

Dr. Baumann recognized that NCES authors established "an exception to their dating rule" for certain circumstances. Tr. at 57; *see also* Tr. at 53, 69-70. Like Dr. Kinsbourne, Dr. Baumann indicated that NCES authors invoked the exception when, in investigating a case child's medical history, they discovered that the child had suffered seizures at any point before the qualifying neurological illness. *See, e.g.*, Tr. at 69-71; *see also* Tr. at 55. Dr. Baumann agreed that if NCES authors considered the child's previous seizures and the child's qualifying neurological illness to be part of a single pathological process, they deemed the date of onset of the qualifying neurological illness to be the date of the first seizure. *See, e.g.*, Tr. at 69-71; *see also* Tr. at 55-57. However, Dr. Baumann disputed Dr. Kinsbourne's interpretation of language in the exception. *See, e.g.*, Tr. at 56-57, 69-74.

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[14] Dr. Baumann received his medical degree from Western Reserve University in Cleveland, Ohio. Respondent's exhibit (R. ex.) C at 1. He is certified by the American Board of Pediatrics, by the American Board of Psychiatry and Neurology with Special Competence in Child Neurology, and by the American College of Epidemiology. *Id.* He belongs to the American Neurological Association and to the Child Neurology Society. *Id.* at 3. He is a Professor of Neurology and Pediatrics at the University of Kentucky, where he is also the Director of the Child Neurology Program. *Id.* at 2.

Dr. Baumann asserted that NCES authors included "purposefully" the example, "'as in cases with progressive mental deterioration,'" in their exception. Tr. at 74, quoting NCES at 147. Citing other language in the NCES section containing the exception, Dr. Baumann advanced that NCES authors expected case children whose seizures appeared to be part of a single pathological process to exhibit from the onset of their seizures continuing, "overt neurologic disease." Tr. at 74; *see also* Tr. at 54, 56-58, 71-73.[15] Dr. Baumann claimed that seizures do not constitute necessarily overt neurological disease. Tr. at 74. Rather, Dr. Baumann said that seizures can be merely "a symptom" of an "abnormality." Tr. at 102.

According to Dr. Baumann, NCES authors anticipated in their "protocol" that "all" children who experienced a qualifying NCES illness would be "admitted" into a hospital for treatment. Tr. at 90; *see also* Tr. at 88, 92-93, 107-08. Because Molly received only limited medical attention in an emergency room for her lengthy seizure in May 1997, Dr. Baumann challenged Dr. Kinsbourne's judgment that Molly's lengthy seizure in May 1997 would have prompted notification to the NCES. *See* Tr. at 90. Nevertheless, Dr. Baumann acknowledged that in August 1997, Molly entered the hospital after suffering a seizure that lasted longer than 30 minutes. *Id.* Dr. Baumann concurred that Molly's August 1997 hospitalization "would have" prompted notification to the NCES "if [Molly] had been in England at the appropriate [time]." *Id.*; *see also* Tr. at 97.

Regardless, Dr. Baumann insisted that Molly's presentation is not eligible for the exception to the general rule that NCES authors used to determine the date of onset of the qualifying neurological illness for each case child accepted into the NCES. *See, e.g.*, Tr. at 55, 57-58, 97, 104-05. Dr. Baumann maintained that although Molly's seizures share likely a common origin, *see, e.g.*, Tr. at 57-58, 75-76, 99, Molly's "excellent medical records" document that Molly appeared intact neurologically following her seizures between September 1996 and August 1997. Tr. at 47-49; *see also* Tr. at 50, 57, 85, 98. Thus, Dr. Baumann concluded that Molly did not manifest between September 1996 and August 1997 "an ongoing underlying neurologic disease" representing a single pathological process. Tr. at 73-75; *see also* Tr. at 47-49, 56-57, 71, 98-99, 103-04. Dr. Baumann noted that Molly's seizure disorder "changed, both clinically and electrically" at some "substantially later" point. Tr. at 85-86. But, Dr. Baumann asserted that Molly's subsequent course is typical for "children in epilepsy." Tr. at 85; *see also* Tr. at 50, 75-76. Moreover, Dr. Baumann proclaimed that if one "accepted" the proposition that NCES authors meant to include seizures with a common origin within the "definition" of the exception, "every child with epilepsy who had a seizure in time relationship to the DPT would have to be considered to have DPT as the [e]tiology." Tr. at 58; *see also* Tr. at 99. And, Dr. Baumann said, "it's quite clear that the authors of the study did not intend" the exception to cover "everyone with epilepsy." Tr. at 99; *see also* Tr. at 58.

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[15] "However, where a child had a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation, the date of onset of that child's illness was regarded as the date of the major convulsion for which the child was admitted to hospital and notified to the Study. The preceding convulsions in these cases were regarded as part of the previous medical history." NCES at 147 (emphasis in original).

Dr. Baumann reviewed briefly NCES results. Dr. Baumann stated that the "small numbers" are "difficult" to interpret. Tr. at 62. Dr. Baumann explained that as a consequence, there exists the "real" prospect that NCES results "could be statistically significant, but not actually true." *Id.* Besides, Dr. Baumann said that NCES results apply only to "the group of subjects in the study," rather than to "individuals." Tr. at 61-62.

Dr. Baumann discussed Dr. Kinsbourne's and Dr. Menkes's theory that endotoxin allows pertussis toxin to breach the blood brain barrier. Dr. Baumann acknowledged that the "part" of the "theory" regarding the neurotoxicity of pertussis and its effect on G proteins "is accepted." Tr. at 94. But, noting that no one has studied the theory even though Dr. Kinsbourne and Dr. Menkes introduced the theory "before" the advent of "the acellular" pertussis vaccine, Dr. Baumann suggested that "people in the field" do not consider the theory to be "biologically plausible." Tr. at 94-95.

DISCUSSION

Congress prohibited special masters from awarding compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason uniformly that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998). The special master has canvassed thoroughly the record. He determines that Molly's medical records alone do not reflect an independent basis for him to conclude more likely than not that Molly's September 17, 1996 DPT vaccination caused actually Molly's intractable seizure disorder accompanied by developmental delay. Thus, Ms. Moberly depends upon Dr. Kinsbourne's opinion to establish her claim.

Through Dr. Kinsbourne, Ms. Moberly poses at least three bases for an actual causation claim. First, Dr. Kinsbourne asserted that medical "literature" and Molly's clinical condition support a conclusion that Molly's September 17, 1996 DPT vaccination caused Molly's condition. Tr. at 10-11; *see also* Tr. at 22-23. Second, Dr. Kinsbourne asserted that epidemiology and Molly's clinical condition support a conclusion that Molly's September 17, 1996 DPT vaccination caused Molly's condition. Tr. at 10-12. Third, Dr. Kinsbourne advanced a biological "mechanism" for Molly's condition. Tr. at 18-20; *see also* Tr. at 27, 31-32.

I.

Dr. Kinsbourne testified that "sufficient literature" shows that "the DPT vaccination is capable of causing, on rare occasion," neurological "damage." Tr. at 11. Dr. Kinsbourne said that Molly's medical records, including EEG reports, demonstrate that Molly's "brain" is "damaged."

Tr. at 11; *see also* Tr. at 21. In Dr. Kinsbourne's view, Molly's condition commenced when Molly exhibited "right and left focal" seizures "[w]ithin 24 hours" after her September 17, 1996 DPT vaccination. Tr. at 9. Dr. Kinsbourne indicated that Molly's medical records do not disclose an alternate cause for Molly's condition. Tr. at 11. Thus, according to Dr. Kinsbourne, Molly's condition is consistent clinically with DPT injury. *Id.*; *see also* Tr. at 22-23.

Except for the NCES--which the special master will address in the next section of this decision--Dr. Kinsbourne did not discuss other literature that buttresses possibly his opinion. Thus, the special master considers an important aspect of Dr. Kinsbourne's opinion to be largely undeveloped. Moreover, the special master is not satisfied completely by Dr. Kinsbourne's description of Molly's initial clinical condition. Dr. Kinsbourne mentioned that Molly exhibited "a fever" with one of the brief seizures following her September 17, 1996 DPT vaccination. Tr. at 9. However, Dr. Kinsbourne did not distinguish *medically* Molly's seizure with fever as a "febrile" seizure. *See, e.g.*, *Bruesewitz v. Secretary of HHS*, No. 95-0266V, 2002 WL 31965744, at *15. And, the special master notes that many special masters have ruled that medical evidence establishes that DPT does not cause "afebrile" seizures. *See, e.g.*, *Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673, at *11; *Salmond v. Secretary of HHS*, No. 91-0123V, 1999 WL 778528, at *10 (Fed. Cl. Spec. Mstr. Sept. 16, 1999); *Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *10; *but see Almeida v. Secretary of HHS*, No. 96-0412V, 1999 WL 1277566, at *21, n.22 (Fed. Cl. Spec. Mstr. Dec. 20, 1999). Thus, the special master is not persuaded by Dr. Kinsbourne's testimony regarding "literature" and Molly's clinical condition.

II.

Relying on the NCES, Dr. Kinsbourne opined that Molly's September 17, 1996 DPT vaccination caused Molly's condition. *See* Tr. at 11-12, 20-21. The NCES presents several distinct, fundamental concepts that are critical in the analysis of a Program case using the test that some special masters have adopted based on the NCES and associated medical literature: children reported to the NCES, or reported children (all children referred to NCES authors by physicians participating in the NCES and by other sources because the children exhibited a suspected NCES condition); children included in the NCES, or case children (those reported children between age two months and 36 months deemed by NCES authors to have exhibited an NCES condition and matched by NCES authors with controls); and children to whom the statistical conclusions of NCES data applied (those case children immunized with DTP within seven days prior to the date of their hospital admission or the estimated date of onset of their illness). The "first hurdle" that Ms. Moberly "must overcome" is demonstrating more likely than not a fictional construct that at some point Molly exhibited a condition that "would have been reported" to NCES authors. *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *15, n.43. If Ms. Moberly clears the "first hurdle," then the second hurdle that Ms. Moberly must overcome is demonstrating more likely than not a fictional construct that NCES authors would have designated Molly as a case child. *See id.* If Ms. Moberly clears the second hurdle, then the third hurdle that Ms. Moberly must overcome is demonstrating more likely than not that the statistical conclusions of NCES data apply to Molly. *See*

id. If Ms. Moberly clears the third hurdle, then the record as a whole must not reflect more likely than not some other identifiable cause for Molly's condition. *See Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672 at *7, 12; *see also Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *12; *Jenkins v. Secretary of HHS*, No. 90-3717V, 1999 WL 476255 at *13; *Raj v. Secretary of HHS*, No. 96-0294V, 2001 WL 963984 at *9.

The parties agree apparently that Molly was intact neurologically when she received her second DPT vaccination on September 17, 1996. In addition, the parties agree certainly that within one year after her September 17, 1996 DPT vaccination, Molly entered the hospital with a condition that would have prompted notification to the NCES. *See* Tr. at 12-13, 90, 97.[16] Further, the parties agree apparently that NCES authors would have accepted Molly as a case child. Molly's age was

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[16] However, the parties dispute which event in Molly's medical history would have prompted notification to the NCES. Dr. Kinsbourne asserted that Molly's prolonged seizure that led to an emergency room visit in May 1997 qualified "definitely" under NCES reporting standards as an NCES condition. Tr. at 12. Dr. Baumann contended that NCES "protocol" contemplated "explicitly" that reported children would be "admitted" into a hospital. Tr. at 90; *see also* Tr. at 88, 92-93, 107-08. Thus, Dr. Baumann asserted that Molly's prolonged seizure that led to a hospital admission in August 1997, rather than Molly's prolonged seizure that led to an emergency room visit in May 1997, qualified under NCES reporting standards as an NCES condition. *See* Tr. at 90. Dr. Kinsbourne did not "disagree at all" with Dr. Baumann's interpretation of NCES protocol. Tr. at 92. But, in Dr. Kinsbourne's view, NCES authors "required hospitalization" for "pragmatic" reasons, "not medical" reasons. *Id.* Dr. Kinsbourne offered that NCES authors "wanted the child to be in a situation where they could gather adequate data for purposes of the study." *Id.* It seems from the plain language of the NCES that NCES authors correlated the medical significance of a neurological illness with hospital admission. After all, the NCES indicates that NCES authors assumed "that children with serious neurological disorders, particularly those severe enough to result in lasting damage to the child, would be admitted to hospital under the care of paediatricians, infectious disease physicians or neurosurgeons." NCES at 101; *see also* NCES at 144 ("In general, however, it seems very unlikely that significant numbers of children with severe or complicated convulsions, acute encephalitis, encephalomyelitis or encephalopathy, unexplained loss of consciousness, or those seriously affected with infantile spasms or Reye's syndrome would not be admitted to hospital under the care of a paediatrician, infectious disease consultant or neurosurgeon."). Therefore, Dr. Baumann's interpretation of NCES protocol appears more correct than Dr. Kinsbourne's interpretation of NCES protocol. Regardless, because Dr. Baumann concedes that an event in Molly's medical history would have prompted notification to the NCES, the resolution of which particular event in Molly's medical history would have prompted notification to the NCES is not crucial to Ms. Moberly's claim. Yet, as part of his deliberation in the case, the special master must judge each expert's facility with the NCES. *See, e.g.*, *Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673, at *3, n.1, *10 (describing in part Dr. Kinsbourne's application of the NCES as unsubstantiated); *Valois v. Secretary of HHS*, No. 97-0433V, 1998 WL 774342, at *5 (Fed. Cl. Spec. Mstr. Oct. 9, 1998)(describing in part Dr. Kinsbourne's application of the NCES as "cavalier").

clearly within "the Study range" when Molly exhibited a condition that satisfied "Study criteria." NCES at 107. Finally, the parties agree apparently that Molly's treating physicians have not determined an etiology for Molly's condition. Thus, Ms. Moberly's case under the test that some special masters have adopted based on the NCES and associated medical literature presents seemingly a single issue: Whether the statistical conclusions of NCES data apply to Molly.

Dr. Kinsbourne recognized that Molly's early presentation in September 1996--two brief seizures within 48 hours after the September 17, 1996 DPT vaccination that did not require immediate medical attention--does "not meet" NCES reporting criteria. Tr. at 12. And, Dr. Kinsbourne recognized that Molly's medical event that would meet NCES reporting criteria, which Dr. Kinsbourne identified as emergent medical care for a prolonged seizure in May 1997, occurred many months after Molly's September 17, 1996 DPT vaccination. *See* Tr. at 12-13. Therefore, Dr. Kinsbourne recognized that under the "general rule" that NCES authors used to date the onset of the qualifying neurological illness for each case child accepted into the NCES--the date of admission for the qualifying neurological illness--the statistical conclusions of NCES data do not apply to Molly. Tr. at 12.

Nevertheless, citing "an exception to the general rule," Dr. Kinsbourne maintained that the statistical conclusions of NCES data apply to Molly. *See* Tr. at 11-13. Dr. Kinsbourne said that NCES authors employed the exception to date the onset of the qualifying neurological illness for each case child accepted into the NCES when the case child had exhibited any seizures before the qualifying neurological illness. *See, e.g.*, Tr. at 13. According to Dr. Kinsbourne, NCES authors used the date "of the first seizure" as the date of onset of the qualifying neurological illness if they believed that the seizures and the qualifying neurological illness "were apparently caused by the same pathological process." Tr. at 13; *see also* Tr. at 42-43. Dr. Kinsbourne asserted that Molly exhibited "a particular" repetitive "seizure pattern." Tr. at 16-17. Therefore, Dr. Kinsbourne opined that "a common pathological process unites" Molly's initial, brief seizures in September 1996 and Molly's later presentation that would have prompted notification to the NCES. Tr. at 13. As a consequence, Dr. Kinsbourne offered that he would "predate" the onset of Molly's condition to Molly's first seizures in September 1996, bringing Molly's condition within critical NCES statistical conclusions. *Id.*

The exception that Dr. Kinsbourne cites appears in a section of the NCES that NCES authors titled "Possible Defects in the Study." NCES at 144-47. In part, NCES authors debated whether NCES protocol yielded an appropriate set of data that, when analyzed, allowed the identification of all "'vaccine-associated' cases." NCES at 146. The authors acknowledged that the "question" was "difficult to answer with confidence." *Id.* NCES authors "discussed" several "illustrative clinical states," including "Repeated Convulsions." *Id.*

NCES authors postulated that "in some cases," a vaccination "might" provoke "a series of events," like "one or more short convulsions," that "might" advance "much later to a serious convulsion, and perhaps to brain damage." NCES at 146; *see also* Tr. at 14. However, NCES authors indicated that their method of analyzing NCES data, "arbitrarily confined to comparing a

history of immunization during the 28 days before admission or onset of illnesses in cases with that in controls," excluded likely from their analysis a number of cases in which the vaccination "triggered" maybe a slowly progressive condition. NCES at 146; *see also* Tr. at 14. NCES authors suggested that the exclusion of the cases from their analysis "might fail to show a true positive relative risk." NCES at 146; *see also* Tr. at 14. Therefore, in their attempt to include all "vaccine-associated" cases in their analysis, NCES authors reviewed each case to determine "whether the child had had any earlier convulsion." NCES at 147; *see also* Tr. at 14. NCES authors instructed:

> When a series of fits appeared to be part of a single pathological process, as in cases with progressive mental deterioration, for the purpose of the Study the *date of onset of illness* was taken to be the *date of the first convulsion*. However, where a child had a series of convulsions *without* any obvious and continuing underlying clinical or pathological explanation, the date of onset of that child's illness was regarded as the date of the major convulsion for which the child was admitted to hospital and notified to the Study. The preceding convulsions in these cases were regarded as part of the previous medical history.

NCES at 147 (emphasis in original); *see also* Tr. at 14.

NCES authors concluded that their guidelines placed those case children whose initial seizures and later NCES illnesses seemed related "amongst [the] count of 'vaccine-associated' cases." NCES at 147; *see also* Tr. at 14.

From his lay perspective, the special master notes that NCES authors vacillated apparently about the propriety of aspects of NCES protocol. *See, e.g.*, NCES at 141, 143, 146-47. While NCES authors maintained that exclusion of certain cases "might fail to show a true positive relative risk," NCES at 146, they conceded that inclusion of "cases" based upon the hypothesis that an "immunization acted" maybe "as a 'trigger' in children who would not otherwise have developed a serious neurological illness" might "overestimate the possible hazards of the vaccine." NCES at 143; *see also* NCES at 141, 144. In their testimony, neither Dr. Kinsbourne nor Dr. Baumann addressed directly the validity of the hypothesis underlying the exception that Dr. Kinsbourne cites.

Regardless, NCES authors provided little, if any, objective information about the process they used to assess cases involving "any earlier convulsion." NCES at 147. NCES authors stated that if they decided that "a series of fits" and the qualifying NCES illness represented "a single pathological process," they considered the "date of the first convulsion" as "the date of onset of illness." *Id.* However, NCES authors did not define explicitly their use of the term "single pathological process." *See id.* And, NCES authors offered just one descriptive example of cases comporting with their concept of a "single pathological process:" cases involving "progressive mental deterioration." *Id.* NCES language implies that NCES authors deemed other cases to reflect "a single pathological process." *See id.*; *see also* Tr. at 38. But, NCES authors were wholly silent on the types of other cases that may have comported with their concept of a "single pathological

process." NCES at 147. Even Dr. Kinsbourne acknowledged the "subjective" character of the "criterion" in NCES "text" containing the exception. Tr. at 17.

Dr. Kinsbourne's testimony highlights particularly the difficulty with applying the NCES in this case. Dr. Kinsbourne expressed readily that the exception that he cites "is not clear." Tr. at 13. Then, Dr. Kinsbourne rejected initially specific language in the exception. Dr. Kinsbourne stated that he does not "find" the descriptive "example of progressive deterioration" that NCES authors included in the exception to be "helpful." Tr. at 34. Rather, Dr. Kinsbourne explained that "progressive deterioration" is not a hallmark of "DPT causation." Tr. at 15; *see also* Tr. at 34, 37-38, 41-42. Dr. Kinsbourne attempted later to attach significance to the example of progressive deterioration. *See* Tr. at 35-37, 41-42. Dr. Kinsbourne said that perhaps NCES authors intended the example of progressive deterioration to denote the loss of "mental skills" as the severity of a seizure disorder increased. Tr. at 35-37; *see also* Tr. at 41-42. Yet, Dr. Kinsbourne acknowledged that NCES authors did not indicate when they expected "progressive mental deterioration" to appear. Tr. at 36.

In the special master's view, Dr. Kinsbourne's testimony about the exception in the NCES was contradictory and confusing. Based upon his evaluation of Dr. Kinsbourne's testimony, the special master decides that in the absence of objective information regarding the process NCES authors used to assess cases involving "any earlier convulsion," attempts to interpret NCES authors' use of the phrase "single pathological process" constitute simply speculation. NCES at 147; *see also* Tr. at 13 (Dr. Kinsbourne: "It is a matter of interpretation as to how one construes what the authors *might* have meant.")(emphasis added). Therefore, the special master concludes that the exception that Dr. Kinsbourne cites is not a suitable basis on which to ground an actual causation claim. Thus, the special master holds that statistical conclusions of NCES data do not apply to Molly.

The special master discusses another, serious, disquieting aspect of Dr. Kinsbourne's testimony. After listening intently to Dr. Kinsbourne's opinion, the special master engaged Dr. Kinsbourne in a colloquy. *See* Tr. at 43-44. The special master noted a dichotomy between Dr. Kinsbourne's opinion and NCES protocol, affecting potentially NCES statistical conclusions. *See id.* The special master stated that if he accepted Dr. Kinsbourne's premise that progressive mental deterioration is not characteristic of DPT injury, he would be constrained to conclude that given NCES protocol, NCES authors counted cases, and based statistical conclusions on cases, that could be in no way related to DPT. *See id.*; *see also* Tr. at 41 Dr. Kinsbourne declared that the special master was "not in the least wrong." Tr. at 44. Indeed, Dr. Kinsbourne proclaimed that the special master's inquiry "opened up a" legitimate, "horrifying panorama" about NCES protocol. *Id.*

In Program practice, "[t]he NCES has been the subject of some controversy." *Sumrall v. Secretary of HHS*, 23 Cl. Ct. 1, 6 (1991); *see also Sharpnack v. Secretary of HHS*, 27 Fed. Cl. 457, 461 (1993); *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387417, at *13 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). Indeed, there exists a split among special masters regarding the evidentiary value of the NCES in Program proceedings. *See, e.g.*, *Estep v. Secretary of HHS*, 28 Fed. Cl. 664, 668-69 (1993). While many special masters "use" the NCES "regularly as a gauge for determining

causation in DPT cases," *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387417 at *13, one special master has criticized sharply and consistently the NCES as "faulty." *Clements v. Secretary of HHS*, No. 95-0484V, 1998 WL 4811881, at *15 (Fed. Cl. Spec. Mstr. July 30, 1998); *see also Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673; *Bruesewitz v. Secretary of HHS*, No. 95-0266V, 2002 WL 31965744; *Valois v. Secretary of HHS*, No. 97-0433V, 1998 WL 774342; *Haim v. Secretary of HHS*, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The special master has studied the multitude of Program cases citing the NCES, the 1991 IOM Report and the 1994 IOM Report. The special master cannot discern in the majority of the cases the extent to which special masters have based decisions upon opinion testimony regarding the NCES and the IOM Reports from *qualified* medical experts and the extent to which special masters have based decisions upon a lay reading of medical literature. *See, e.g.*, *Sharpnack v. Secretary of HHS*, No. 90-0983V, 1992 WL 167255 (Cl. Ct. Spec. Mstr. July 28, 1992); *Liable v. Secretary of HHS*, No. 98-0120V, 2000 WL 1517672. The distinction is vital. In *Abbott v. Secretary of HHS*, 27 Fed. Cl. 792 (1993), the United States Court of Federal Claims counseled that "Congress intended [the Act] to be understood--and to be applied--as it would be by a medical professional." *Id.* at 794. During his tenure, the special master has learned well that medical studies and medical texts are written by, and for, medical professionals. Medical studies and medical texts express medical concepts through a "vocabulary" of "specialization" and "words of art that carry their own precise and special meaning." *Id.* at 793-94. Thus, a lay reader cannot presume to accord "common usage" to language in medical studies and medical texts. *Id.* at 793. Rather, a lay reader must approach medical studies and medical texts through the prism of medical knowledge.

The special master grants that following the lead of a number of his colleagues, he adopted in a previous case the NCES, finding that "[t]he IOM has endorsed the NCES." *See Eiss v. Secretary of HHS*, No. 97-0529V, Decision on Entitlement and Damages at 22 (Fed. Cl. Spec. Mstr. Mar. 9, 2005).[17] However, as a frequent witness for petitioners in Program cases, Dr. Kinsbourne possesses a solid reputation. And, Dr. Kinsbourne's testimony about the NCES in this case revives for the special master substantive concerns about the viability of the NCES as an element of proof of causation-in-fact in a Program case. Thus, with this decision, the special master signals an important shift in his analysis of actual causation cases involving the NCES. The special master does not contemplate entertaining an actual causation claim based upon the NCES absent a comprehensive

[17] In *Eiss*, the child exhibited within 72 hours after a Tetramune vaccination unusual, persistent irritability that preceded a cascade of neurological symptoms culminating in hospitalization approximately five weeks after the Tetramune vaccination. *See generally Eiss v. Secretary of HHS*, No. 97-0529V, Decision on Entitlement and Damages (Fed. Cl. Spec. Mstr. Mar. 9, 2005). The special master determined that the unusual, persistent irritability represented the first acute neurological symptom of an encephalopathy within the context of NCES case definitions. *See generally Eiss v. Secretary of HHS*, No. 97-0529V, Decision on Entitlement and Damages (Fed. Cl. Spec. Mstr. Mar. 9, 2005). The special master held that NCES statistical conclusions applied to the child. *See generally Eiss v. Secretary of HHS*, No. 97-0529V, Decision on Entitlement and Damages (Fed. Cl. Spec. Mstr. Mar. 9, 2005).

presentation from a medical expert regarding NCES design; NCES method; NCES conclusions and IOM reviews of the NCES.

III.

Dr. Kinsbourne posited that on occasion, two components of pertussis vaccine--endotoxin and pertussis toxin--may operate in conjunction to cause neurological damage. Tr. at 19; *see also* Tr. at 26-27. Dr. Kinsbourne explained that by "increasing the permeability of the walls of blood vessels," endotoxin allows possibly pertussis toxin to breach "the blood brain barrier" and to bind "to the surface of neurons," especially "G proteins." Tr. at 18-19; *see also* Tr. at 26-28. Dr. Kinsbourne explained further that if pertussis toxin binds to G proteins, the pertussis toxin is capable of neutralizing G proteins, leading to cell damage or cell death. Tr. at 18-19.

Dr. Kinsbourne asserted that many aspects of his blood brain barrier theory are well-established. Tr. at 28. Indeed, Dr. Baumann confirmed the effect of pertussis toxin on G proteins. Tr. at 94. Nevertheless, Dr. Kinsbourne conceded that his blood brain barrier theory has not been tested. Tr. at 27; *see also* Tr. at 29. Moreover, Dr. Kinsbourne acknowledged that Molly's medical records do not contain any evidence supporting the application of his blood brain barrier theory in Molly's case. Tr. at 32. Therefore, the special master decides that the utility of Dr. Kinsbourne's blood brain barrier theory as an element of proof of causation-in-fact in this case is dubious. The special master's conclusion is consonant certainly with numerous Program decisions. *See, e.g.*, *Borin v. Secretary of HHS*, No. 99-0491V, 2003 WL 21439673 at *11; *Terran v. Secretary of HHS*, No. 95-0451V, 1998 WL 55290 at *11; *Sumrall*, 23 Cl. Ct. at 6; *but see Almeida v. Secretary of HHS*, No. 96-0412V, 1999 WL 1277566 at *12-14; *Misenko v. Secretary of HHS*, No. 92-0013V, 1995 WL 761436 (Fed. Cl. Spec. Mstr. Dec. 7, 1995).

VI.

The special master discusses briefly a potential, fourth basis for an actual causation claim. Ms. Moberly may contend that some combination of the evidence that she has submitted establishes more likely than not that Molly's September 17, 1996 DPT vaccination caused actually Molly's intractable seizure disorder. Yet, as the special master's decision reflects surely, the special master deems much of Ms. Moberly's evidence to be infirm. And, as the special master's decision reflects surely, the special master is not impressed that Dr. Kinsbourne has expressed credibly and rationally an opinion using the disparate elements of the evidence. Thus, the special master decides that the evidence as a whole does not demonstrate affirmatively a logical sequence of cause and effect.

CONCLUSION

The special master is exceedingly sympathetic to Ms. Moberly's and Molly's circumstances. Nevertheless, on the record before him, the special master determines that there is not a preponderance of the evidence that Molly's September 17, 1996 DPT vaccination caused actually Molly's condition. Therefore, the special master holds that Ms. Moberly is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Ms. Moberly's copy of this decision to Ms. Moberly by overnight express delivery.

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John F. Edwards
Special Master